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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/596,141

Applicant(s)

LAWN ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 21-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 7. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-55 are still at issue and are present for examination. Claims 1-20 are now under consideration. Claims 21-55 remain withdrawn from consideration as being drawn to non-elected invention.

#### ***Election/Restrictions***

Applicant's election of Group I, claims 1-20 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-20 of this application. Upon perusal of all the three provisional application upon which the priority dates are claimed, Examiner found that none of them provide adequate support fro SEQ ID NO:3 or its fragments. None of the provisional applications disclose SEQ ID NO:3.

#### ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

***Specification***

The disclosure is objected to because of the following informalities: The amendments filed on 12-30-02, paper No.13/B are not in proper format. Furthermore, amendments requested to be made on pages 59 and 76 do not match with the paragraphs in the specification and therefore has not been entered. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA comprising SEQ ID NO:3 or DNA comprising specific fragments of SEQ ID NO:3 and having the promoter activity, does not reasonably provide enablement for any DNA comprising a sequence that hybridizes under stringent conditions (claims 4-5) or is 80% identical to SEQ ID NO:3 or its specific fragments (as claimed in claim 2 and 3) including variants, mutants and recombinants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the

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prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 4-7 are so broad as to encompass any polynucleotide comprising DNA which simply hybridizes under stringent conditions to SEQ ID NO:3 or its specific fragments or which is 80% similar to SEQ ID NO:3 or its specific fragments. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA sequences that are broadly encompassed by the claims.

The applicants propose to use the above polynucleotides as a promoter and identify compounds that can affect that activity. However, applicants have not shown that sequences which simply hybridizes under stringent conditions to SEQ ID NO:3 or its specific fragments or that are 80% identical to either SEQ ID NO:3 or its specific fragments continue to have such promoter activity. Since only the specific nucleotide sequence of SEQ ID NO:3 and its specific fragments determines the promoter activity, changing the nucleotide sequences as proposed by the applicants and/or addition of substantial amount of additional nucleotide sequence unrelated to the nucleic acid sequence of SEQ ID NO:3 may not lead to desired function of the polynucleotides. This is because the changes suggested by the applicants will result in an enormous number of nucleotide sequences that may or may not exhibit the very same promoter activity. The disclosure is limited to polynucleotides comprising only SEQ ID NO:3 or its specific fragments.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or modifications of nucleotides, as encompassed by the instant claims, and the base changes within a nucleic acid's sequence can be made with a reasonable

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expectation of success in obtaining the desired activity/utility are limited and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given DNA to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA comprising SEQ ID NO:3 or its specific fragments because the specification does not establish: (A) regions of the DNA sequence which may be modified without effecting the above mentioned activity/utility; (B) the general tolerance of ABC1 promoter DNA sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide in SEQ ID NO:3 with an expectation of obtaining the desired biological function and utility; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA comprising a polynucleotide having 80% identity to SEQ ID NO:3 or its specific fragments. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising either SEQ ID NO:3, fragments of SEQ ID NO:3 (as claimed in claims 2 and 3) or polynucleotides that are 80% identical to the above polynucleotides.

The specification does not contain any disclosure of the structure and function of all DNA sequences that are encompassed by the claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins and also having different structures. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification does not disclose even a representative number of species of the claimed genus with specific structure and function which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Birren et al. (GenBank Accession No. AC012230, 4-22-00). This rejection is based upon the public availability of a printed publication. Claim 3 of the instant application is drawn to polynucleotides comprising nucleotides 1394-1532 of SEQ ID NO:3. Birren et al. disclose such a polynucleotide comprising nucleotides 1394-1532 of SEQ ID NO:3 (see enclosed sequence alignment). Therefore, Birren et al. anticipate claim 3 as written.

Claims 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (GenBank Accession No. AA527406, 8-21-1997). This rejection is based upon the public availability of a printed publication. Claims 4-5 of the instant application are drawn to polynucleotides that hybridize to SEQ ID NO:3 or fragments of SEQ ID NO:3 (as claimed in claim 2) under stringent conditions. NCI-CGAP disclose a nucleotide which is 99.1% identical to a stretch of SEQ ID NO:3 and is therefore capable of hybridizing under stringent condition (see enclosed sequence alignment). Therefore, NCI-CGAP anticipate claims 4-5 as written.



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Claims 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosier-Montus et al. (WO 01/83746, published in English on 11-8-01, filed on 5-2-01 designating US with US priority date 5-2-00 and GenBank Accession No. AX351029 and AX351031). This rejection is based upon the public availability of a printed PCT publication. Claims 4-7 of the instant application are drawn to polynucleotides that hybridize to SEQ ID NO:3 or fragments of SEQ ID NO:3 (as claimed in claim 2) under stringent conditions and polynucleotides comprising nucleotide sequences that are at least 80% identical SEQ ID NO:3 or specific fragments claimed in claim 2. Rosier-Montus et al. disclose a polynucleotide comprising nucleotide which is 89 or 90% identical to SEQ ID NO:3 and nucleotides 1-1532 of SEQ ID NO:3 respectively (see enclosed sequence alignments). The reference nucleotide sequence is capable of hybridizing under stringent conditions to the above claimed polynucleotides. Therefore, Rosier-Montus et al. anticipate claims 4-7 as written. In response to the above rejection, applicants may argue that the above reference is not a valid reference as it is post-dated. However, such an argument would not be persuasive to overcome the above rejection as Examiner has not granted the priority date claimed by the applicants, the above reference is a valid prior art reference.

### ***Conclusion***

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

A handwritten signature in black ink, appearing to read 'Manjunath' with a stylized flourish at the end.

Manjunath N. Rao  
March 7, 2003